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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,956	09/30/2003	Christopher Don Roberts	55491-20008.00	1045

38706 7590 05/02/2006

FOLEY & LARDNER LLP
1530 PAGE MILL ROAD
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EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/676,956	Applicant(s) ROBERTS ET AL.	
	Examiner L. E. Crane	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8,9,12-13, and 15-31 is/are rejected.
- 7) ☒ Claim(s) 17,23 and 28 is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/4/04, 2/14/05</u> . | 6) <input type="checkbox"/> Other: ____ |

Note to applicant: when a rejection refers to a claim X at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

The Abstract of the Disclosure is objected to because it does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

The Abstract is too brief to properly disclose the subject matter of the application.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

No claims have been cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been added as of the date of this Office action. Two Information Disclosure Statement (2 IDSs) filed October 4, 2004 and February 14, 2005 have been received with all cited references and made of record. The sequence information disclosure and diskette received February 3, 2004, was found acceptable and entered into the PTO database on July 6, 2004.

Claims 1-33 remain in the case.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-3, 8, 9, 12-13 and 15-33** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-2, 5-6 and 8-10** of allowed copending Application No. **10/821,638**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds being claimed are directed to the same or patentably indistinguishable pyrrolo[2,3-**d**]pyrimidines and the pharmaceutical compositions thereof in both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **17, 23 and 28** are objected to under 35 C.F.R. §1.75(c), as being in improper dependent form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP §608.01(n). Accordingly, **17, 23 and 28** have not been further treated on the merits.

Because there are numerous different patentably distinguishable subject matters in addition to the subject matter noted in the rejection above, found within the instant claims, the following written restriction requirement is also entered herein.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims **4-7**, drawn to 6-N-hydroxy or alkoxy-2,8-disubstitutedadenosines, 5'-adenylates and other 5'-derivatives compounds, classified in Class 536, subclass 027.630.

II. Claims **8-9**, drawn to pyrrolo[2,3-**d**]pyrimidine nucleoside and nucleotide analogues, classified in Class 536, subclass 027.200.

III. Claims 10-11, drawn to pyrazolo[3,4-**d**]pyrimidine nucleoside and nucleotide analogues, classified in Class 536, subclass 027.200.

IV. Claims 14, drawn to 6-N-attached N-heterocyclo-2,8-disubstitutedadenosines wherein the heterocyclo function is part of a ring linked back to the N⁶-nitrogen, analogous 5'-adenylates and other 5'-derivatives compounds, classified in Class 536, subclass 027.210.

Claims 1-3, 12-13 and 15-33 link inventions I, II, III and IV and will be examined with the elected invention to the extent to which they apply.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant inventions are directed to structurally different sets of molecules, N⁶,2,8-trisubstituted adenosines and their 5'-derivatives, and pyrrolo[2,3-**d**]pyrimidine nucleoside and nucleotide analogues, which have different arrangement of functionalities and therefore will have different medicinal effects.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant inventions are directed to structurally different sets of molecules, N⁶,2,8-trisubstituted adenosines and their 5'-derivatives, and pyrazalo[3,4-**d**]pyrimidine nucleoside and nucleotide analogues, which have different arrangement of functionalities and therefore will have different medicinal effects.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant inventions are directed to structurally different sets of molecules, N⁶,2,8-trisubstituted adenosines and their 5'-derivatives, and 6-N-attached N-heterocyclo-2,8-disubstitutedadenosines wherein the heterocyclo function is part of a ring linked back to the

N⁶-nitrogen, analogous 5'-adenylates and other 5'-derivatives compounds, which have different arrangement of functionalities and therefore will have different medicinal effects.

Inventions **II and III** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant inventions are directed to structurally different sets of molecules, pyrrolo[2,3-**d**]pyrimidine nucleoside and nucleotide analogues, and pyrazalo[3,4-**d**]pyrimidine nucleoside and nucleotide analogues, which have different arrangement of functionalities and therefore will have different medicinal effects.

Inventions **II and IV** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant inventions are directed to structurally different sets of molecules, pyrrolo[2,3-**d**]pyrimidine nucleoside and nucleotide analogues and 6-N-attached N-heterocyclo-2,8-disubstitutedadenosines wherein the heterocyclo function is part of a ring linked back to the N⁶-nitrogen, analogous 5'-adenylates and other 5'-derivatives compounds, which have different arrangement of functionalities and therefore will have different medicinal effects.

Inventions **III and IV** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant inventions are directed to structurally different sets of molecules, pyrazalo[3,4-**d**]pyrimidine nucleoside and nucleotide analogues and 6-N-attached N-heterocyclo-2,8-disubstitutedadenosines wherein the heterocyclo function is part of a ring linked back to the N⁶-nitrogen, analogous 5'-adenylates and other 5'-derivatives compounds, which have different arrangement of functionalities and therefore will have different medicinal effects.

Because these inventions are distinct for the reasons given above and 1) have acquired a separate status in the art as shown by their divergent classification, 2) have acquired a separate status in the art because of their recognized divergent subject matter, and 3) the search

required for each of Groups **II and III** are not required for any one of the other Groups, restriction for examination purposes as indicated is proper.

A telephone call was made to Foley & Lardner on April 30, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. §1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(h).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

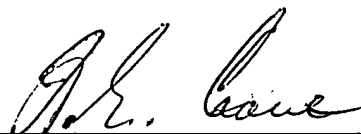
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
05/01/2006

A handwritten signature in cursive script, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.
Patent Examiner
Technology Center 1600